DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

San Francisco District
1431 Harbor Bay Parkway
Alameda, CA 94502-7070
Telephone: 510/337-6700

VIA FEDERAL EXPRESS
Our Reference: 2953834

August 9, 2002

Uwe Henze, President/ Partner
H.U.G. Inc. dba Gourmet Foods Inc.
2557 Barrington Court
Hayward, California 94545

WARNING LETTER

Dear Mr. Henze:

On October 9, 10, and 12, 2001, we inspected your seafood processing facility, located at 2557 Barrington Court, Hayward, CA. We found that you had serious deviations from the seafood HACCP regulations in Title 21, Code of Federal Regulations, Part 123 (21 CFR 123). In accordance with 21 CFR 123.6(g), failure of a processor to have and implement a HACCP plan that complies with this section or otherwise operate in accordance with the requirements of this part, renders your ready-to-eat and ready-to-cook products containing seafood ingredients adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). Accordingly, your ready-to-eat and ready-to-cook products were adulterated, in that the fishery products had been prepared, packed, and held under insanitary conditions whereby they may have been rendered injurious to health. You may find the Act, the seafood HACCP regulations, and the Fish & Fisheries Products Hazards & Controls Guidance, 3rd edition, June 2001, through links in FDA's home page at www.fda.gov See the attached handout, which gives information on how to obtain the Fish & Fisheries Products Hazards & Controls Guidance, 3rd edition, June 2001, which is available on-line.

Your serious HACCP deviations are as follows:

1 You must have a HACCP plan that, at a minimum, lists the critical limits that must be met to comply with 21 CFR 123.6(c)(3). A critical limit is defined in 21 CFR 123.3(c) as "the maximum or minimum value to which a physical, biological, or chemical parameter must be controlled at a critical control point to prevent, eliminate, or reduce to an acceptable level the occurrence of the identified food safety hazard."

   a However, your firm's HACCP plans for ready-to-cook and ready-to-eat products did not list critical limits for refrigerated products at the receiving critical control

point to control pathogen growth and toxin formation. The critical limit in your HACCP plans did not include how pathogen growth and toxin formation was controlled during the transportation of microbiologically-sensitive product.

b. Your firm's HACCP plan for ready-to-eat products lists a critical limit, "Must be properly cooked at required temp--Seafood 145 F min" at the cooking critical control point that is not adequate to control bacterial pathogen growth. The critical limit is missing the time of exposure at 145°F. The FDA provides guidance on appropriate critical limits for a cooking critical control point in the Fish & Fisheries Products Hazards & Controls Guidance, 3rd edition, June 2001. It suggests a time parameter of 17 minutes at 145° F to inactivate *Listeria monocytogenes*, a heat-tolerant vegetative pathogen, or conducting a scientific study establishing the cook process.

2. You must take an appropriate corrective action when a deviation from a critical limit occurs to comply with 21 CFR 123.7(a). However, according to your records, you did not take a corrective action when the refrigerator temperature exceeded 40° F on 6/19/01, 6/20/01, 6/21/01, and 6/27/01. The corrective action must address both the implicated products and the cause of the deviation.

3. You must conduct a hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur and have a HACCP plan that, at a minimum, lists the food safety hazards that are reasonably likely to occur to comply with 21 CFR 123.6(a) and 123.6(c)(1). A food safety hazard is defined in 21 CFR 123.3(f) as "any biological, chemical, or phsical property that may cause a food to be unsafe for human consumption."

   a. However, your firm's HACCP plans for both ready-to-eat and ready-to-cook products did not list the food safety hazard of sulfites in lobster.

   b. However, your firm's HACCP plans for both ready-to-eat and ready-to-cook products did not list the food safety hazards of:

      (1) Pathogen growth and toxin formation in microbiologically-sensitive raw ingredients, in-process product, *Clostridium botulinum* in smoked fish and caviar at the refrigerated storage process step.

      (2) Scombrotoxin (histamine) formation in mahi mahi and tuna at the refrigerated storage process step.

      (3) Pathogen growth and toxin formation (e.g., *Clostridium botulinum* and *Listeria monocytogenes*) at the thawing process step

4 Since you chose to include corrective actions in your HACCP plan, your described correction actions must be appropriate, to comply with 21 CFR 123.7(b). However, your

corrective action plan for ready-to-cook and cooked ready-to-eat foods did not list how the cause of the deviation would be corrected.

At the conclusion of the inspection, the deviations were listed on Form FDA 483 (Inspectional Observations) and discussed with you. A copy of this form is enclosed for your ready reference. This list is not meant to be an all-inclusive list of violations. You are responsible for ensuring that your processing facility operates in compliance with the Act, the Seafood HACCP regulations, and the Good Manufacturing Practice regulations (21 CFR 110).

Over 10 months have elapsed since the FDA inspection. You have had sufficient time to correct the violations. We may take further action if you have not corrected these violations. For instance, we may take move to seize your products and/or enjoin your firm from operating.

Please respond in writing within fifteen (15) working days of receipt of this letter of the specific steps you have taken to correct the deviations conveyed to you by FDA at the close of the inspection. Your response should outline the specific things you have done and are doing to correct the above-listed deviaitons. You may wish to include in your response documentation that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay, and state when you will correct any remaining deviations.

Your response should be directed to: Ms. Harumi Kishida, Compliance Officer, U.S. Food and Drug Administration, 1431 Harbor Bay Parkway, Alameda, CA 94502-7070. If you have any questions regarding any issue in this letter, please contact Ms. Kishida at (510) 337-6824.

Sincerely,

Dennis K. Linsley
District Director
San Francisco District

Enclosures:
Form FDA 483
Handout on Fish & Fisheries Products Hazards & Controls Guidance, 3rd edition

cc: Dale H. Bailey, Operations Manager